Teleflex Medical Group Headquarters
2345 Waukegan Road
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Phone: 847-572-8002
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510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Introducer Assembly with Rotator Lock

K060519

A. Name, Address, Phone and Fax Number of Applicant

Teleflex Medical Group Headquarters
2345 Waukegan Road, Suite 140
Bannockburn, IL 60015 USA
Phone: 847-572-8002
Fax: 847-572-8001

MAY - 5 2006

B. Contact Person

Lori Hays
Senior Manager, Regulatory Affairs

C. Date Prepared

February 24, 2006

D. Device Name

Trade Name: Introducer Assembly with Rotator Lock

Common Name: Catheter Introducer

Classification Name: Catheter Introducer

Product Code: DYB

Regulation Number: 870.1340

Class: II

E. Device Description

The Introducer Assembly with Rotator Lock consists of a dilator and a split sheath introducer that is used to provide access to the venous system for device entry, when used in conjunction with additional percutaneous entry devices.

F. Intended Use

The Introducer Assembly with Rotator Lock is intended to provide access to the venous system for device entry, when used in conjunction with additional percutaneous entry devices.

G. Substantial Equivalence

The Introducer Assembly with Rotator Lock is substantially equivalent to the TFX Medical Introducer Assembly (K993191) with respect to functionality, design, placement and use.

H. Summary of Testing

All materials used in the fabrication of the Introducer Assembly with Rotator Lock were evaluated through biological qualification safety tests as outlined in ISO 10993 Part 1 "Biological Evaluation of Medical Devices". Verification and Validation testing was performed according to the risk analysis. The design and materials were found to be acceptable for the intended use

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 5 2006

Teleflex Medical Group Headquarters
c/o Ms. Lori Hays
Senior Manager, Regulatory Affairs
2345 Waukegan Road, Suite 140
Bannockburn, IL 60015

Re: K060519
Introducer Assembly with Rotator Lock
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: II
Product Code: DYB
Dated: April 6, 2006
Received: April 10, 2006

Dear Ms. Hays:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna R. Lochner

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use

K060519

510(k) Number (if known): K060519

Device Name: Introducer Assembly with Rotator Lock

Indications For Use:

The Introducer Assembly with Rotator Lock is intended to provide access to the venous system for device entry, when used in conjunction with additional percutaneous entry devices.

Prescription Use ___X___ (21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division R. Jackson

(Division Sign-Off)

Division of Cardiovascular Devices

510(k) Number K060519